

ICLUSIG could be the difference in treating chronic myeloid leukemia (CML)



What is ICLUSIG?

ICLUSIG is a prescription medicine used to treat adults who have:

- Chronic Myeloid Leukemia (CML)
 - chronic phase CML who did not tolerate or no longer benefit from treatment with at least 2 prior kinase inhibitor medicines
 - accelerated phase or blast phase CML who cannot receive any other kinase inhibitor medicines
 - a specific type of abnormal gene (T315I-positive) chronic phase, accelerated phase, or blast phase

ICLUSIG is not for use to treat people with newly diagnosed chronic phase CML.

It is not known if ICLUSIG is safe and effective in children.

Please see Important Safety Information on pages [10-13](#) and [20-23](#) and read the [Medication Guide](#), including serious warnings, in the full [Prescribing Information](#).

Take the next step in treating your CML with ICLUSIG

If your current treatment is no longer working to control **chronic myeloid leukemia (CML)**, your doctor may recommend ICLUSIG[®] (ponatinib).

ICLUSIG is a **tyrosine kinase inhibitor (TKI)** medication (sometimes referred to as a kinase inhibitor) proven to help people who have had to switch treatments. It has been shown to help people regain control of CML and keep **BCR-ABL1** levels low.

Keep reading to find out if ICLUSIG may be the right next step for you. Be sure to talk to your doctor about your treatment goals and your treatment plan.

Images throughout this brochure are not of actual patients.



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ICLUSIG can cause serious side effects, including:

Blood clots or blockage in your blood vessels (arteries and veins).

Blood clots or blockage in your blood vessels may lead to heart attack, stroke, or death. You may need emergency surgery or treatment in a hospital.

Heart problems. ICLUSIG can cause heart problems, including heart failure, which can be serious and may lead to death.

Liver problems. ICLUSIG can cause liver problems, including liver failure, which can be severe and may lead to death.

See **“What is the most important information I should know about ICLUSIG[®] (ponatinib)?”** on page [10](#) for more information.

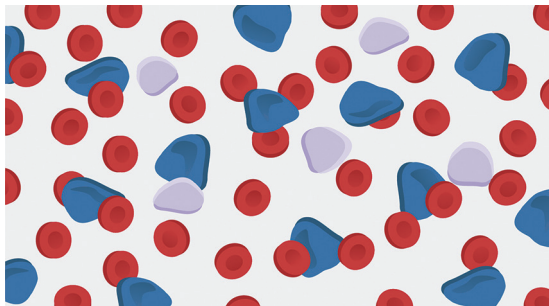
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Overview of CML

CML starts with an abnormal change, or **mutation**, in a cell's **DNA** that creates a chromosome known as the **Philadelphia (Ph) chromosome**.

- When the Ph chromosome is present in cells, a protein known as **BCR-ABL1** is produced
- The BCR-ABL1 protein causes the bone marrow to produce abnormal white blood cells
- These abnormal cells are CML cells. Over time, they overtake healthy white blood cells in the bone marrow to cause leukemia

In CML, abnormal cells crowd out healthy cells in the bone marrow.



- Red blood cells
- Abnormal white blood cells
- Healthy white blood cells

CML is a progressive disease. There are 3 phases, or stages, of CML that represent different levels of progression. Ranging from least severe to most severe, the phases are:

- Chronic phase
- Accelerated phase
- Blast phase

Most people with CML are diagnosed in chronic phase.



An important goal of chronic phase CML treatment is to prevent progression to accelerated phase and/or blast phase.



Learn more about ICLUSIG[®] (ponatinib), including how it works and how it may help, on pages [14-19](#).

Please see Important Safety Information on pages [10-13](#) and [20-23](#) and read the Medication Guide, including serious warnings, in the full [Prescribing Information](#).

Treating CML with TKI therapy


Many people with CML are treated with a type of targeted therapy known as a **TKI**, or **tyrosine kinase inhibitor**. The protein that causes CML, BCR-ABL1, is a tyrosine kinase protein. The TKIs used to treat CML specifically inhibit BCR-ABL1. They help stop abnormal white blood cells, or CML cells, from forming in the body.




Monitoring your response to treatment

The goal of CML treatment is to keep your levels of BCR-ABL1 as low as possible. This can help reduce the number of CML cells in your body. Your doctor may do **molecular** or **cytogenetic tests** on cells from your bone marrow or blood to see how well a treatment is working.

One term your healthcare provider may use to describe the results of these tests is **log reduction**. This is a measure of how much BCR-ABL1 levels have been lowered. Log reductions typically mean a treatment is working well to control CML. For example:

 A 1-log reduction means there are **10 times** fewer CML cells compared with the start of treatment (baseline). So the percentage of cells with BCR-ABL1 has been reduced to **10%**

 A 2-log reduction means there are **100 times** fewer CML cells compared with the start of treatment (baseline). So the percentage of cells with BCR-ABL1 has been reduced to **1%**



Understand what tests you are taking and what the results mean. Take notes during your appointments so you can keep track of important information.

Please see Important Safety Information on pages [10- 13](#) and [20-23](#) and read the Medication Guide, including serious warnings, in the full Prescribing Information.

Why you may need to switch your current treatment

An important goal of treating CML is to reduce the number of leukemia cells in the body. TKI treatments may work well to do this. In some cases however, after a period of time, CML may stop responding to a particular TKI treatment. This is known as **treatment resistance**.



If your CML becomes **resistant** to a TKI treatment, your doctor may recommend switching to a new TKI.



Another reason your doctor may recommend switching TKIs is **intolerance** to side effects caused by your current treatment.



If your doctor recommends switching treatments, ask whether ICLUSIG[®] (ponatinib) may be the next step for you.

How mutations may affect treatment options

In CML, changes called **mutations** can appear in the BCR-ABL1 protein during TKI treatment. This can cause the treatment to stop working.

If you develop a mutation while on your current treatment, your doctor may recommend that you switch to a different TKI that may work better against the mutation.

T315I is a type of mutation that can occur in CML. ICLUSIG was the first TKI to be approved to treat people with the T315I mutation.

ICLUSIG may help patients who are resistant to prior therapy, whether or not they have a mutation.



Please see Important Safety Information on pages **10-13** and **20-23** and read the **Medication Guide**, including serious warnings, in the full **Prescribing Information**.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ICLUSIG[®] (ponatinib)?

ICLUSIG can cause serious side effects, including:

Blood clots or blockage in your blood vessels (arteries and veins).

Blood clots or blockage in your blood vessels may lead to heart attack, stroke, or death. A blood clot or blockage in your blood vessels can prevent proper blood flow to your heart, brain, bowels (intestines), legs, eyes, and other parts of your body. You may need emergency surgery or treatment in a hospital. Get medical help right away if you get any of the following symptoms:

- chest pain or pressure
- pain in your arms, legs, back, neck or jaw
- shortness of breath
- numbness or weakness on one side of your body
- leg swelling
- trouble talking
- headache
- dizziness
- severe stomach area pain
- decreased vision or loss of vision

Blood clots or blockage in your blood vessels can happen in people with or without risk factors for heart and blood vessel disease, including people 50 years of age or younger. The most common risk factors for these problems are a history of high blood pressure (hypertension), high cholesterol, and heart disease. Blood clots or blockages in your blood vessels happen more often in people as they get older, and in people with a history of decreased blood flow, high blood pressure, diabetes, or high cholesterol.

Heart problems. ICLUSIG can cause heart problems, including heart failure which can be serious and may lead to death. Heart failure means your heart does not pump blood well enough. ICLUSIG can also cause irregular, slow, or fast heartbeats and heart attack. Your healthcare provider will check you for heart problems during your treatment with ICLUSIG. Get medical help right away if you get any of the following symptoms: shortness of breath, chest pain, fast or irregular heartbeats, dizziness, or feel faint.

Liver problems. ICLUSIG can cause liver problems, including liver failure, which can be severe and may lead to death. Your healthcare provider will do blood tests before and during your treatment with ICLUSIG to check for liver problems. Get medical help right away if you get any of these symptoms of liver problems during treatment:

- yellowing of your skin or the white part of your eyes
- dark "tea-colored" urine
- sleepiness
- loss of appetite
- bleeding or bruising

See **“What are the possible side effects of ICLUSIG?”** on page 20 for information about side effects.

Before you take ICLUSIG, tell your healthcare provider about all of your medical conditions, including if you:

- have a history of blood clots in your blood vessels (arteries or veins)
- have heart problems, including heart failure, irregular heartbeats, and QT prolongation
- have diabetes
- have a history of high cholesterol
- have liver problems
- have had inflammation of your pancreas (pancreatitis)
- have high blood pressure
- have bleeding problems
- plan to have surgery or have had a recent surgery. You should stop taking ICLUSIG at least 1 week before planned surgery. See **“What are the possible side effects of ICLUSIG?”** on page 20.



Be sure to tell your doctor about any side effects you have while taking ICLUSIG.

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IMPORTANT SAFETY INFORMATION (continued)

- are lactose (milk sugar) intolerant. ICLUSIG tablets contain lactose.
- eat grapefruit or drink grapefruit juice. See **“How should I take ICLUSIG?”** on page 24.
- are pregnant or plan to become pregnant. ICLUSIG can harm your unborn baby.
 - Your healthcare provider will do a pregnancy test before you start taking ICLUSIG.
 - **For females who can become pregnant:**
 - Use an effective form of birth control during treatment and for **3 weeks** after your last dose of ICLUSIG.
 - Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with ICLUSIG.
 - ICLUSIG may affect your ability to have children. Tell your healthcare provider if this is a concern for you.
- are breastfeeding or plan to breastfeed. It is not known if ICLUSIG passes into your breast milk. **Do not** breastfeed during treatment and for **1 week** after your last dose of ICLUSIG.

Tell your healthcare provider about all the medicines you take, including prescription medicines and over-the-counter medicines, vitamins, and herbal supplements. ICLUSIG and other medicines may affect each other causing side effects.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take ICLUSIG?

- Take ICLUSIG exactly as your healthcare provider tells you to take it.
- Do not change your dose or stop taking ICLUSIG unless your healthcare provider tells you.
- Swallow ICLUSIG tablets whole. Do not crush, break, cut, chew or dissolve ICLUSIG tablets.
- Take ICLUSIG with or without food.

- Do not eat grapefruit or drink grapefruit juice during treatment with ICLUSIG.
- If you miss a dose of ICLUSIG, take your next dose at your regularly scheduled time the next day. Do not take 2 doses at the same time to make up for a missed dose.
- If you take too much ICLUSIG, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of ICLUSIG?

ICLUSIG may cause serious side effects, including:

- See **“What is the most important information I should know about ICLUSIG?”** on page 10.
- **High blood pressure (hypertension).** High blood pressure is common during treatment with ICLUSIG and can also be serious or severe. ICLUSIG can cause new or worsening high blood pressure. Your blood pressure should be checked regularly, and any high blood pressure should be treated during treatment with ICLUSIG. Tell your healthcare provider right away if you get confusion, headaches, dizziness, chest pain or shortness of breath.
- **Inflammation of the pancreas (pancreatitis).** Pancreatitis is common during treatment with ICLUSIG and can also be serious or severe. Tell your healthcare provider right away if you get any of the following symptoms: sudden stomach-area pain or discomfort, nausea, and vomiting. Your healthcare provider should do blood tests to check for pancreatitis during treatment with ICLUSIG.
- **Neuropathy.** ICLUSIG may cause damage to the nerves in your arms, brain, hands, legs, or feet (neuropathy). Tell your healthcare provider right away if you get any of these symptoms during treatment with ICLUSIG:
 - muscle weakness, tingling, burning, pain, discomfort or loss of feeling in your hands and feet

Please see Important Safety Information on pages 10-13 and 20-23 and read the Medication Guide, including serious warnings, in the full Prescribing Information.

Understanding ICLUSIG and how it works

ICLUSIG[®] (ponatinib) is a prescription medicine used to treat adults who have:

- chronic phase CML who did not tolerate or no longer benefit from treatment with at least 2 prior kinase inhibitor medicines
- accelerated phase or blast phase CML who cannot receive any other kinase inhibitor medicines
- a specific type of abnormal gene (T315I-positive) chronic phase, accelerated phase, or blast phase

ICLUSIG is not for use to treat people with newly diagnosed chronic phase CML.

It is not known if ICLUSIG is safe and effective in children.



ICLUSIG works by stopping the BCR-ABL1 protein

ICLUSIG helps to stop cancer-causing BCR-ABL1 proteins from creating CML cells. ICLUSIG has been shown to work even if these proteins have developed a type of mutation called the T315I mutation.

Talk to your doctor about whether ICLUSIG may be the next step in treating your CML.



Medication is only one part of your treatment. Don't be afraid to ask for help from friends and family when you feel you need it.

Please see Important Safety Information on pages [10-13](#) and [20-23](#) and read the Medication Guide, including serious warnings, in the full [Prescribing Information](#).

How ICLUSIG may help

ICLUSIG[®] (ponatinib) was shown to help keep BCR-ABL1 levels low in patients whose previous CML TKI medicines no longer worked, or who had to switch because of serious side effects.

ONGOING STUDY WITH ICLUSIG IN CP-CML

An ongoing study evaluates the efficacy, safety, and dosing of ICLUSIG

This study includes patients with chronic phase CML who:

- have taken at least 2 prior TKI medicines
- or
- have a mutation known as the T315I mutation



In this study, 94 patients started on 45 mg orally once daily of ICLUSIG and were reduced to 15 mg orally once daily upon achieving a response.*

*Defined as a reduction in BCR-ABL1 to less than or equal to 1%. Also known as a 2-log reduction.

Of patients who achieved a response with ICLUSIG:

44% of patients (41 of 93 patients) achieved BCR-ABL1 less than or equal to 1% at 12 months.[†]



62% (28 of 45 patients) continued to see benefit from ICLUSIG for at least 90 days after their dose was reduced.

Every patient is different. Results may vary.

[†]You may hear your doctor refer to this as a 2-log reduction. See page Z.

Please see Important Safety Information on pages 10-13 and 20-23 and read the Medication Guide, including serious warnings, in the full Prescribing Information.

5-YEAR STUDY WITH ICLUSIG

In a 5-year study, ICLUSIG was shown to help patients control CML

This study included patients with:

- **Chronic phase CML (CP-CML)**
- **Accelerated phase CML (AP-CML)**
- **Blast phase CML (BP-CML)**
- **Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)**

All patients started on 45 mg orally once daily of ICLUSIG[®] (ponatinib).



By 12 months, patients with CP-CML achieved the following results:

55% of patients achieved **MAJOR CYTOGENETIC RESPONSE (MCyR):**

In 148 out of 267 patients, 0% to 35% of tested cells had the Ph chromosome.

46% of patients achieved **COMPLETE CYTOGENETIC RESPONSE (CCyR):**

In 123 out of 267 patients, none of the tested cells had the Ph chromosome.



AT 5 YEARS, ICLUSIG was

still helping patients

who saw results in the first year of treatment.

Of 148 patients with CP-CML who achieved MCyR by 12 months, an estimated 82% would continue to achieve this result at 5 years.

Many of these patients maintained MCyR even when their dose of ICLUSIG was reduced.

Every patient is different. Results may vary.



Talk to your doctor about these results to learn more about how ICLUSIG was studied and how it could be a part of your treatment plan.

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IMPORTANT SAFETY INFORMATION (continued)

- double vision and other problems with eyesight, trouble moving the eye, drooping of part of the face, sagging or drooping eyelids, or change in taste
- **Eye problems.** Serious eye problems that can lead to blindness or blurred vision may happen with ICLUSIG. Tell your healthcare provider right away if you get any of the following symptoms: bleeding in the eye, perceived flashes of light, light sensitivity, floaters, blurred vision, dry, inflamed, swollen, or itchy eyes, or eye pain. Your healthcare provider will monitor your vision before and during your treatment with ICLUSIG.
- **Bleeding.** Bleeding is common during treatment with ICLUSIG and can also be serious and may lead to death. Tell your healthcare provider right away if you get any signs of bleeding during treatment with ICLUSIG including:
 - vomiting blood or if your vomit looks like coffee-grounds
 - pink or brown urine
 - red or black (looks like tar) stools
 - coughing up blood or blood clots
 - unusual bleeding or bruising of your skin
 - menstrual bleeding that is heavier than normal
 - unusual vaginal bleeding
 - nose bleeds that happen often
 - drowsiness or difficulty being awakened
 - confusion
 - headache
 - change in speech
- **Fluid retention.** Your body may hold too much fluid (fluid retention) which can be serious and may lead to death. Tell your healthcare provider right away if you get any of these symptoms during treatment with ICLUSIG:
 - swelling of your hands, ankles, feet, face, or all over your body
 - weight gain
 - shortness of breath and cough
- **Irregular heartbeat.** ICLUSIG may cause an irregular heartbeat. Tell your healthcare provider right away if you experience loss of

consciousness, fainting, dizziness, chest pain or palpitations.

- **Low blood cell counts.** ICLUSIG may cause low blood cell counts, which can be severe. Your healthcare provider will check your blood counts regularly during treatment with ICLUSIG. Tell your healthcare provider right away if you have a fever or any signs of an infection while taking ICLUSIG.
- **Tumor Lysis Syndrome (TLS).** TLS is caused by a fast breakdown of cancer cells. TLS can cause you to have kidney failure and the need for dialysis treatment, and an abnormal heartbeat. Your healthcare provider may do blood tests to check for TLS. Drink plenty of water during treatment with ICLUSIG to help reduce your risk of getting TLS. Call your healthcare provider or get emergency help right away if you get any of the following symptoms during treatment with ICLUSIG:
 - nausea and vomiting
 - weakness
 - swelling
 - shortness of breath
 - muscle cramps
 - seizures
- **Reversible Posterior Leukoencephalopathy Syndrome (RPLS – also known as Posterior Reversible Encephalopathy Syndrome).** ICLUSIG may trigger a condition called RPLS. Call your healthcare provider right away if you get headaches, seizures, confusion, changes in vision or problems thinking.
- **Wound healing problems.** Wound healing problems have happened in some people who take ICLUSIG. Tell your healthcare provider if you plan to have any surgery before or during treatment with ICLUSIG.
 - You should stop taking ICLUSIG at least 1 week before planned surgery.
 - Your healthcare provider should tell you when you may start taking ICLUSIG again after surgery.

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IMPORTANT SAFETY INFORMATION (continued)

- **A tear in your stomach or intestinal wall (perforation).** Tell your healthcare provider right away if you get:
 - severe pain in your stomach-area (abdomen)
 - swelling of the abdomen
 - high fever

The most common side effects of ICLUSIG when given alone include:

- skin rash
- joint pain
- stomach-area (abdomen) pain
- headache
- constipation
- dry skin
- tiredness
- swelling of your hands, ankles, feet, face, or all over your body (fluid retention and edema)
- fever
- nausea
- increase in lipase levels (a blood test done to check your pancreas)
- low hemoglobin in the blood (anemia)
- liver problems
- blood clots or blockage in blood vessels (arteries)
- low blood platelet counts
- low blood levels of white blood cells

The most common side effects of ICLUSIG when given with chemotherapy include:

- liver problems
- joint pain
- skin rash
- headache
- fever
- stomach-area (abdomen) pain
- constipation
- tiredness
- nausea
- mouth sores
- increase in lipase levels (a blood test done to check your pancreas)
- numbness, or tingling (pins and needles), pain, or weakness in the hands or feet
- fever due to low white blood cell counts (febrile neutropenia)
- swelling of your hands, ankles, feet, face, or all over your body (fluid retention and edema)
- vomiting

- irregular heartbeat
- low blood levels of white blood cells
- low blood platelet counts
- low hemoglobin in the blood (anemia)
- changes in liver function tests

Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with ICLUSIG if you have certain side effects.

Tell your healthcare provider if you have any side effect that bothers you or does not go away.

These are not all of the possible side effects of ICLUSIG. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects.

To report SUSPECTED SIDE EFFECTS, contact Takeda at 1-844-817-6468 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.



Your doctor may change your dose, or stop ICLUSIG temporarily or permanently, if you have certain side effects.

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How to take ICLUSIG

ICLUSIG IS TAKEN



as one tablet



once a day



with or without food

The recommended starting dose of ICLUSIG[®] (ponatinib) is 45 mg orally once a day. For patients with chronic phase or accelerated phase CML, your doctor may reduce the dose if ICLUSIG is working for you. Your doctor may stop ICLUSIG if you experience side effects or do not respond to treatment.

How should I take ICLUSIG?

- Take ICLUSIG exactly as your healthcare provider tells you to take it.
- Do not change your dose or stop taking ICLUSIG unless your healthcare provider tells you.
- Swallow ICLUSIG tablets whole. Do not crush, break, cut, chew or dissolve ICLUSIG tablets.
- Take ICLUSIG with or without food.
- Do not eat grapefruit or drink grapefruit juice during treatment with ICLUSIG.
- If you miss a dose of ICLUSIG, take your next dose at your regularly scheduled time the next day. Do not take 2 doses at the same time to make up for a missed dose.
- If you take too much ICLUSIG, call your healthcare provider or go to the nearest hospital emergency room right away.



It's important to take ICLUSIG as your doctor tells you in order to see potential results. Do not change your dose or stop taking ICLUSIG unless your doctor instructs you to. Tell your doctor about any side effects you may experience.

Talk to your doctor about ICLUSIG

It's normal to have questions about CML treatment. That's why it's important to work closely with your healthcare team and understand your treatment plan.



Talk to your doctor about the information you've read here. And be sure to ask questions like:

- Is ICLUSIG the right next step for me?
- How can ICLUSIG help control CML?
- What is the recommended dose of ICLUSIG?
- What are the side effects of ICLUSIG?

Working closely with your healthcare team can help you remain confident as you continue to take on CML.

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Glossary

Accelerated phase CML: The second phase of CML progression, when the number of blast cells has increased.

BCR-ABL1: An abnormal protein that causes too many abnormal white blood cells (leukemia, or CML, cells) to be made. Sometimes referred to as BCR-ABL1^{IS}.

BCR-ABL1 mutations: Changes to the BCR-ABL1 protein that stop certain TKIs from working.

Blast phase CML: The third and final phase of CML progression. This phase has the highest number of blast cells, or immature blood cells, in the blood and bone marrow. It can be life-threatening.

Chronic myeloid leukemia (CML): A type of blood cancer in the bone marrow that grows slowly. It causes too many white blood cells to form.

Chronic phase CML: The first phase of CML, when there are more white blood cells than normal. There may not be symptoms in this phase.

Cytogenetic testing: A test that looks for changes in chromosomes (the part of the cell that contains genetic information).

Complete cytogenetic response (CCyR): Treatment response where BCR-ABL1 levels are 0.1% to 1%, or the Philadelphia chromosome is absent.

DNA: Deoxyribonucleic acid. The genetic information carried by cells.

Intolerance: When treatment with a drug must be stopped because of side effects.

Log reduction: A measure of how much BCR-ABL1 levels have been lowered.

Major cytogenetic response (MCyR): Treatment response when about one-third (35%) or fewer cells have the Philadelphia chromosome.

Molecular testing: A sensitive test that can measure very small amounts of BCR-ABL1 in the blood. It is sometimes referred to as a qPCR test.

Mutation: An abnormal change in the DNA of a cell, particularly common in cancer cells.

Mutation testing: Tests used to see if samples of DNA have changed, or mutated.

Philadelphia (Ph) chromosome: An abnormal chromosome that forms in CML. It contains the BCR-ABL1 gene.

Resistance (or resistant): When cancer does not respond to a treatment.

T315I: A type of BCR-ABL1 mutation that prevents cancer cells from responding to certain TKI treatments.

Tyrosine kinase inhibitor (TKI): A type of medicine that stops the growth of CML cells by blocking, or “inhibiting,” BCR-ABL1.



To learn more about ICLUSIG[®] (ponatinib), talk to your healthcare provider or visit [ICLUSIG.com](https://www.iclusig.com).

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We're here for you throughout your treatment



From helping you understand coverage options to identifying available financial assistance, Takeda Oncology Here2Assist® is committed to offering you comprehensive support throughout your treatment journey.

- Works with your insurance company to help you get started on your medication
- Identifies available financial assistance that may be right for you
- Connects you to additional support services and resources
- Identifies specialty pharmacies to help fill and ship your prescriptions appropriately
- Conducts regular follow-up calls with you

Need help finding additional support services? We're here to help.

Let's Talk. Call us at **1-844-817-6468**, Option 2. We're available Monday-Friday, 8AM-8PM ET. To learn more about Takeda Oncology Here2Assist, visit www.Here2Assist.com.



ONCOLOGY

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